

**Application No.: 10/510,401**  
**Filing Date: May 12, 2005**

## **REMARKS**

Claim 1 has been amended. New claim 32 has been added. Support for new claim 32 may be found in the specification at page 27, Table 7; page 22, Tables 1-2; and page 27, Table 6. Thus, no new matter has been introduced by these amendments. Reconsideration and withdrawal of the present rejections in view of the amendments and comments presented herein are respectfully requested.

### Rejection under 35 U.S.C. §112, first paragraph

Claims 7 and 16 were rejected under 35 U.S.C. §112, first paragraph as allegedly not being enabled. Specifically, the Examiner stated that the specification does not disclose a repeatable process to obtain the microorganism(s), and it is not clear from the specification or record that the microorganism(s) is/are readily available to the public.

M.P.E.P. 2404.01 states that:

"In an application where the invention required access to specific biological material, an applicant could show that the biological material is accessible because it is known and readily available to the public. The concepts of "known and readily available" are considered to reflect a level of public accessibility to a necessary component of an invention disclosure that is consistent with an ability to make and use the invention. To avoid the need for a deposit on this basis, the biological material must be both known and readily available."

*Thermus aquaticus* LMG 8924 is available from the American Type Culture Collection (ATCC) under accession number 25104. As evidenced by the enclosed e-mail from the Bacteriology Program Manager of the ATCC (Exhibit A), LMG 8924 (accession number 25104) was deposited with the ATCC on December 30, 1968, long before the priority date of the present application (April 5, 2002). A current search of the ATCC database revealed that this strain is still available.

In addition, *Thermus aquaticus* LMG 8924 was deposited in 1989 at the Belgian Coordinated Collection of Microorganisms (BCCM) by the NCIMB Collection (the National Collection of Industrial, Marine and Food Bacteria, U.K.). It is listed in the catalogue of the BCCM, and is publicly available from BCCM to any *bona fide* individual, operating in a professional environment suitable for handling material of the biohazard group involved, under the conditions of the BBCM Material Transfer Agreement.

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*Bacillus licheniformis* LMG 7561 is available from the Belgian Coordinated Collection of Microorganisms (BCCM). As evidenced by the enclosed page from the BCCM online catalog (Exhibit B), LMG 7561 was deposited with the BCCM in 1986, long before the priority date of the present application, and is currently available from the BCCM. It is listed in the online catalogue of the BCCM and publicly available to any *bona fide* individual, operating in a professional environment suitable for handling material of the biohazard group involved, under the conditions of the BBCM Material Transfer Agreement.

As evidenced by the enclosed reference (Harvey et al., *System. Appl. Microbiol.* **24**:277-284, 2001; Exhibit C), several strains of *Thermoactinomyces vulgaris* were publicly available from the ATCC before the priority date of the present application (April 5, 2002). At page 278, under "Materials and Methods", this reference states that the following ATCC strains of *T. vulgaris* were used: ATCC 43649T, 15733, 15734 and 21364. A current search of the ATCC database revealed that these strains are still available.

Thus, Applicants have satisfied the enablement requirement by showing that the microorganisms recited in the claims are known and readily available to the public. In view of the comments presented above, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

Rejection under 35 U.S.C. §112, second paragraph

Claims 1-9 were rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite. Specifically, the Examiner contended that the recitation of "a sufficiently effective amount" was unclear. Claim 1 as amended recites adding "an amount of at least one intermediate thermostable and/or thermostable serine protease which is effective to prevent or retard staling," thus clarifying Applicants' intention. One or ordinary skill in the art can readily determine amounts which will be effective to prevent or retard staling based on the guidance provided in the specification, including the examples provided therein (see specification at pages 21-22 and 25-27).

In view of the comments provided above, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

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Rejection under 35 U.S.C. § 102(b)

Claims 1, 6, 7, 9, 10, 13-16 and 18 were rejected as allegedly being anticipated by Klingenberg et al. (DD 156,714 A). The Examiner states that Klingenberg et al. teaches a heat stable thermitase from *Thermoactinomyces vulgaris*, and that the method and the improver would inherently prevent or retard staling during the baking process of the bakery products.

Enclosed herewith as Exhibit D is an English Translation of Klingenberg et al. This reference discloses a method for large-scale production of a thermophilic protease (Thermitase) from *Thermoactinomyces vulgaris*, and states that this Thermitase is used for gluten breakdown in bakery products. Claim 1 as amended recites:

A method for the prevention or retarding of staling during the baking process of bakery products which comprises the step of adding an amount of at least one intermediate thermostable and/or thermostable serine protease which is effective to prevent or retard staling in said bakery products. (Emphasis added).

Although the cited reference mentions that the *T. vulgaris* Thermitase promotes gluten breakdown in bakery products, it neither discloses nor suggests that this Thermitase can be used to prevent or retard staling during the baking process of the bakery products. Thus, this reference does not teach adding “an amount of at least one intermediate thermostable and/or thermostable serine protease which is effective to prevent or retard staling” as recited in the present claims. Since Klingenberg et al. do not address the problem of bread staling, they do not teach addition of an effective prevention or retarding of staling amount, or for that matter any particular amount, of *T. vulgaris* Thermitase. One cannot properly infer that the method disclosed by Klingenberg et al. would necessarily result in prevention or retardation of staling as recited in the present claims, since the reference does not teach that *T. vulgaris* Thermitase is added in an amount effective to prevent or retard staling. In fact, this reference teaches only a crude preparation containing the Thermitase, and does not teach a method for isolation/purification of Thermitase, and therefore does not teach any specific amounts of Thermitase. Thus, the cited reference does not teach any specific amounts of Thermitase, even for use in gluten breakdown.

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According to M.P.E.P. § 2112 IV, to support a rejection based on inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the characteristic alleged to be inherent by the Examiner necessarily flows from the teachings of the applied prior art. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). (emphasis added) "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." (emphasis added) *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient!'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). (emphasis added).

The use of *T. vulgaris* Thermitase in amounts effective to prevent or retard staling in bakery products does not necessarily flow from the teachings of Klingenberg et al., since this reference: (1) does not teach or suggest staling of bakery products; and (2) does not teach or suggest any specific amounts of *T. vulgaris* Thermitase, including an amount that would prevent or retard staling. Thus, this missing descriptive matter is not necessarily present in the method described in the reference. Thus, the claims relating to the method/improver for preventing or retarding staling cannot be anticipated by this reference.

In view of the comments presented above, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

Rejections under 35 U.S.C. § 103(a)

Claims 3, 4, 8, 12, 17, 25, 27, 30 and 31 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Klingenberg et al. in view of Oleson et al. (US 6,110,508)

Claims 7 and 16 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Klingenberg et al. in view of Terada et al. (US 5,124,261) and Chernoglazov et al. (RU 2,177,799).

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Claims 2, 5, 11, 23, 24, 26, 28 and 29 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Klingenberg et al. in view of Stetter (US 5,714,373)

In order for a claim to be rendered obvious, each element of the claim must be disclosed within the cited references. As discussed above, Klingenberg et al. neither disclose nor suggest that *T. vulgaris* Thermitase, or any thermostable serine protease, can be used to prevent or retard staling during the baking process of the bakery products.

Oleson et al. discloses addition of lipases to bakery products, and that a protease can also be added for gluten weakening. However, this reference does not teach thermostable proteases, or prevention or retardation of staling.

Terada et al. teaches a process for production of the heat-resistant alkaline protease aqualysin I from *Thermus aquaticus*. This enzyme is disclosed to be used as an additive to detergents and as a component of bioreactors. This reference neither teaches nor suggests that this enzyme can be added to bakery products.

Chernoglavov et al. disclose production of keratinase from *Bacillus licheniformis* which can be used in the food industry. This reference neither teaches nor suggests any effective amounts of this enzyme, or that it can be added to bakery products, or that it can be used to prevent or retard staling.

Stetter et al. discloses production of a thermostable protease from *Thermococcus AV4*, and that such proteases are “useful in a variety of industrial applications.” This reference neither teaches nor suggests that this enzyme can be added to bakery products.

Thus, none of the secondary references remedy the defect in the teaching of Klingenberg et al., namely adding an effective prevention or retarding of staling amount of at least one intermediate thermostable and/or thermostable serine protease to a bakery product.

In view of the comments presented above, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a)

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather,

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any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

### **CONCLUSION**

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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